ATSDR's Toxicological Profiles: A Potential for Use in Site Evaluations

Deborah A. Barsotti, Ph.D., D.A.B.T.
Ralph C. O'Connor, Jr., Ph.D.
William Cibulas, Jr., Ph.D.
Agency for Toxic Substances and Disease Registry
Atlanta, Georgia

ABSTRACT

CERCLA as amended requires the Agency for Toxic Substances and Disease Registry (ATSDR) to prepare toxicological profiles for the 275 most hazardous substances found at National Priority List (NPL) sites. A major purpose of these profiles is to provide guidance to public health professionals who must mitigate exposure and address health concerns for persons who live near hazardous waste sites. Each profile is required to include an examination, summary, and interpretation of available toxicological information and epidemiologic evaluations. The information and data are to be used to determine the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of being developed. In this paper, we explain: (1) how the toxicological profiles have been structured to enable the public health professional to evaluate the potential threat to human health from exposure to these chemicals at hazardous waste sites; (2) how public comments on drafts of the first 25 profiles have resulted in improvements to the drafts of the second group of 25 profiles; and (3) how additional information needed to determine the levels of significant human exposure for a chemical will be obtained through a health effects research program ATSDR has developed in consultation with the Environmental Protection Agency (EPA) and the National Toxicology Program (NTP).

INTRODUCTION

The Superfund Amendments and Reauthorization Act of 1986 (SARA) extended and amended CERCLA. SARA directed the Agency for Toxic Substances and Disease Registry (ATSDR) to prepare toxicological profiles for hazardous substances that are most commonly found at facilities on the CERCLA NPL and that pose the most significant potential threat to human health, as determined by ATSDR and the U.S. EPA. Section 110 (3) of SARA directs the Administrator of ATSDR to prepare a toxicological profile for each of the substances that the agencies have determined to be the most hazardous. In each profile, ATSDR is directed to do the following:

- Examine, summarize, and interpret the available toxicological information and epidemiologic evaluations on a hazardous substance to ascertain the levels of significant human exposure for the substance and the associated acute, subacute, and chronic health effects;
- Determine whether adequate information on the health effects of each substance is available or in the process of being developed to determine levels of exposure that present a significant risk to human health of acute, subacute, and chronic health effects; and
- Where appropriate, identify toxicological testing needed to identify the types or levels of exposure that may present significant risk of adverse health effects in humans.

Those involved with assessing the risks that hazardous waste sites pose to human health should consider four basic concepts(1): hazard identification, dose-response assessment, exposure assessment, and risk characterization. Toxicology and epidemiology serve as the scientific basis for these considerations; thus ATSDR's Toxicological Profiles potentially may be used as a major reference for those involved in these activities.

PUBLIC HEALTH STATEMENT

Purpose of Public Health Statement

In the process of developing the profiles, ATSDR examined its experiences in performing health assessments while asking the following questions:

- What type of information is most often needed when an individual is assessing a particular site?
- What type of information is most often requested by the affected public?

To achieve the goal of communicating pertinent toxicological information to the principal audiences for the profiles (i.e., professionals at the federal, state, and local levels, interested private sector organizations and groups, and members of the public), each toxicological profile starts with a public health statement which, in non-technical language, presents the substance's relevant toxicological properties. ATSDR chose to relay this information in a question-and-answer format. An example of the contents of the public health statement is given below.

- What is Chemical X?
- How might I be exposed to Chemical X?
- How does Chemical X get into my body?
- How does Chemical X affect my health?
- Is there a medical test to determine if I have been exposed to Chemical X?
- What levels of exposure have resulted in harmful health effects?
- What recommendations has the Federal Government made to protect human health?

Practical Application of Public Health Statement

Once a hazardous material has been identified at a site, citizens are concerned about the potential adverse health effects of this situation. Their informational needs differ from those of other audiences. Therefore, the public health statement may be removed from the rest of the document and convey to the general lay public the substantive public health concerns associated with the hazardous substances. These statements provide the officials associated with

potential or realized hazardous sites an important resource of information for the concerned public.

THE BODY OF THE TOXICOLOGICAL PROFILE

Purpose of the Toxicological Profile

In contrast to the Public Health Statement, the remainder of the Toxicological Profile is designed to serve the informational needs of other audiences. The remaining chapters of the toxicological profile were developed in sufficient detail to meet the needs of health professionals for current toxicological information on individual hazardous substances. Included in the profile are chapters entitled "Health Effects Summary," "Chemical and Physical Information," "Toxicological Data," "Manufacture, Import, Use and Disposal," "Environmental Fate," "Potential for Human Exposure," "Analytical Methods," and "Regulatory and Advisory Status."

Practical Application of the Toxicological Profiles

The hazardous chemical is characterized by including key elements of the identification and description of all the various adverse health effects that it may produce, the dose-response relationships for each of these effects, and the mechanisms by which they produce them. The toxicological profile provides information pertaining to different exposure conditions with special emphasis on the route of exposure, a key for evaluating the potential health effects once the specific human exposure pathways have been identified. Consider the following example. A pregnant woman who lives in a community adjacent to a hazardous waste site is informed that her drinking water supply is contaminated with Chemical X. She contacts a state health official with concerns about her unborn child. The official goes to the Toxicological Profile, which is oriented first by route of exposure and then by end-point. The profile helps the state health official to discover quickly whether any information on reproductive/developmental effects of oral exposure to Chemical X is available and, if so, what levels and durations of exposure have caused those effects.

A major goal of ATSDR's toxicological profiles is to provide toxicological information in a manner that will enable the public health professional to evaluate the potential threat to human health from exposure to the chemicals at hazardous waste sites. At the present, this goal is accomplished by providing a single, complete current reference for the hazard evaluation of that particular substance.

PUBLIC COMMENT

ATSDR distributed approximately a thousand draft copies of each of the first 25 toxicological profiles. During the 90-day period allowed for public comment, 107 individuals or organizations submitted written comments on the draft profiles. The number of commenters per profile ranged from 14 (on lead) to 2 on benzo(b)fluoranthene. Commenters were from industry (33%), state agencies (15%), federal agencies (13%), trade associations (11%), academic institutions (11%), consulting firms (10%), and international sources (4%). Many of these comments were used to revise the draft profiles into the final versions that are now available from the National Technical Information Service (NTIS). In addition to comments on specific profiles, ATSDR received many comments that could be applied to many or all of the profiles. These generic comments were used to redesign the second group of 25 profiles.

RESEARCH NEEDS

For longer range purposes, the profiles identify toxicological data needs for which research programs will be designed and initiated pursuant to the requirements of section 110 of SARA. In answering the often-asked questions in the public health statement and evaluating the existing data for other chapters of the profile, ATSDR is confronted with the problem of how much or, more often, how little is known about these hazardous materials. This is true particularly regarding mechanisms to assess exposure as well as the risk posed to human health in Superfund site situations, i.e., low-level chronic exposure(s). To help highlight these issues, ATSDR has identified selected research needs and future directions for research:[2]

- Environmental Epidemiology
- Exposure Assessment
- Toxicology
- Risk Assessment
- Surveillance
- Health Education.

These needs and directions reflect ATSDR's experience in dealing with health assessments and do not necessarily reflect other agencies' needs and directions.

The importance of this process should not be underestimated. ATSDR, with cooperation from NTP and EPA, will assess the need for exposure and toxicity data required to reduce the uncertainties of risk assessment. Most importantly, ATSDR is directed to initiate research programs for the purpose of filling these needs. The information derived from the research would allow the site evaluator to more accurately assess the hazards posed by the material, thus reducing the uncertainty of risk assessments. More practically, the research results should help provide answers to those often-asked and most difficult questions "What is this chemical going to do to me?" and "Will this chemical have any effect on my children?"

CONCLUSIONS

Because site evaluations are specific to individual waste sites having their own characteristics, ATSDR's Toxicological Profiles contain the pertinent information on individual hazardous substances that will aid the evaluator in characterizing the public health implications. Thus, ATSDR's Toxicological Profiles become pivotal for conducting activities associated with the five elements of disease prevention associated with hazardous substances in the general environment.[2] These elements are as follows:

- Identification of health problems and concerns
- Evaluation of adverse health effects and concerns
- Control of adverse health effects
- Dissemination of information
- Infrastructure to effect prevention strategies.

Since ATSDR's Toxicological Profiles are not static, the Agency is looking constantly for ways to improve the communication of toxicological information to the users. One means of receiving suggestions for improvement comes from the public comment periods allowed for each document. Another mechanism for obtaining input would be by direct solicitation of comments from public health officials. ATSDR looks to continued growth in its activities for protecting human health associated with environmental hazardous substances.

REFERENCES

1. National Research Council, *Risk Assessment in the Federal Government: Managing the Process*. A report of the Committee on the Institutional Means for Assessment of Risks to Public Health, National Academy Press, Washington, D.C. p. 192, 1983.
2. Johnson, B. L. "Public Health Effects of Hazardous Waste in the Environment," in *Hazardous Waste: Detection, Control, Treatment*, ed., R. Abbou, pp. 1017-1035 , Elsevier, The Netherlands, 1988.